



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/776,190    01/24/97    JOSEL

H    P564-7002

EXAMINER

HM12/0427

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WASHINGTON DC 20005-5701

RICIGLIANO, J

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

04/27/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/776,190

Applicant(s)

Josel et al.

Examiner

Joseph W. Ricigliano Ph. D.

Group Art Unit

1627



☒ Responsive to communication(s) filed on Jan 28, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 72-99 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 72-99 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions

### ***Election/Restriction***

1. This application contains claims directed to patentably distinct species of the claimed invention.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 72-89, drawn to a product conjugate, classified in at least class 530, subclasses 300+ and class 536 subclass 22.1+
- II. Claims 95-99, drawn to a biospecific binding and immunoassay methods, classified in at least class 435, subclass 4+ (especially subclass 6) and class 436, subclass 501+, 506+ 518+, 536+ and 543+.
- III. Claims 90-94, drawn to a processes of preparing a conjugate, classified in at least class 530, subclass 333+ and class 536 subclass 25.3+

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the product can be used to raise antibodies by injection into a subject animal.

4. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by different processes such as by linking to the previously prepared peptided to hetero-bifunctional crosslinking agents with one reactive moiety, and subsequently attaching haptens etc. to the unmodified group of the linker.

5. Inventions II and III are related as distinct processes. The processes are distinct as the processes have different steps, (e.g., attachment of haptens to the carrier in group II as opposed to the binding assay steps wherein the immunoassay is correlated with the amount of binding partner) Moreover, the processes used different reagents (synthetic reagents as opposed to binding assay reagents) and produce different outcomes, a product carrier as opposed to an immunoassay result indicating the presence of an analyte.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required each Group is not coextensive, restriction for examination purposes as indicated is proper.

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6. This application contains claims directed to the following patentably distinct species of the claimed invention:

7. If applicant elects the invention of group I applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently group I contains claims directed to the following patentably distinct species of the claimed invention comprised of the following subspecies:

A: Subspecies of synthetically made polymeric carrier/ monomeric units selected from nucleotides, nucleotide analogues and amino acids.

B: Subspecies of hapten molecules selected from the group consisting of at least: hormones, vitamins and neurotransmitters, peptides, nucleic acids etc.

C: Subspecies of marker or solid phase binding groups selected from those disclosed including at least luminescent metal chelates and fluorescent groups etc.

A proper election of species requires a selection from subspecies A-C.

The species differ with respect to their chemical composition and the structure of the conjugates. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 72 is generic to group I.

8. If applicant elects the invention of group II applicant is required under 35 U.S.C. 121 to elect a single species of synthetically made polymeric carrier/ monomeric units (conjugate) selected from nucleotides, nucleotide analogues and amino acids.

# BACKFILE DOCUMENT INDEX SHEET

Misc. Income

37

PCT Papers in a 371 App.

A...

Amendment Including Elections

ABST

Abstract

ADS

Application Data Sheet

AF/D

Affidavit or Exhibit Received

APPENDIX

NPL

Patent Literature

OATH

Declaration

PET.

Sp.

MAIL

Specification No.

TRN

Transmittal New Application

CTNF

Count Non-Final

CTRS

Count Restriction

326-00 EXIN 1

Examiner Interview

M903

DO/EO Acceptance

M905

DO/EO Missing Requirement

NFDR

Formal Drawing Required

NOA

Notice of Allowance

PETDEC

Decision

**OUTGOING**

CTMS  
Misc. Office Action

Misc. Office \_\_\_\_\_ 1449 \_\_\_\_\_  
Signed 1449 \_\_\_\_\_ 892 \_\_\_\_\_  
892 \_\_\_\_\_

892  
ABN  
Abandonment

APDEC  
Board of Appeals Decision

Board of Appeals Decision  
APEA  
Minor Answer

Examiner Answer

CTAV

Advisory Action

Count Advisory Action  
CTEQ  
Ex parte Quayle

Count Ex parte Quayle  
CTFR  
Rejection

Count Final Rejection

ECB  
Copy Box Id

Evidence Copy Box Id  
WC  
Worksheet

Claim Worksheet

Free Worksheet

Appeal Brief \_\_\_\_\_  
C.A.D. \_\_\_\_\_  
Change of Address \_\_\_\_\_  
N/A/P \_\_\_\_\_  
Notice of Appeal \_\_\_\_\_  
PA... \_\_\_\_\_  
Change in Power of Attorney \_\_\_\_\_  
REM \_\_\_\_\_  
Applicant Remarks in Amendment \_\_\_\_\_  
XT/ \_\_\_\_\_  
Extension of Time filed separate \_\_\_\_\_

## File Wrapper

FWCLM  
File Wrapper Claim

IIFW  
File Wrapper Issue Information

SRFW  
File Wrapper Search Info

IDS Including 1449

**Internal**

Examiner Search Notes SRNT

PTO Prepared Complete Claim Set CLMPTO

Evidence Copy Box Identification ECBOX

Claim Worksheet WCLM

Fee Worksheet WFEE

90	Applicant(s)  Josel et al.
igliano Ph. D.	Group Art Unit 1627

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21 to elect a single disclosed species for  
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p III applicant is required under 35

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nucleotide analogues and amino acids.

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21 to elect a single disclosed species for  
ns shall be restricted if no generic claim is  
n 90 is generic to group III.

his requirement must include an identification of the claim, the date the claim was made, the date this requirement, and a listing of all claims made by the claimant. An argument that a claim is not responsive unless accompanied by a listing of all claims made by the claimant is

m, applicant will be entitled to consideration  
 ten in dependent form or otherwise include  
 n as provided by 37 CFR 1.141. If claims are  
 ate which are readable upon the elected

and that the species are not patentably  
identify such evidence now of record  
or clearly admit on the record that this is the

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Ricigliano Ph. D. whose telephone number is (703) 308-9346. The examiner can be reached on Monday through Thursday from 7:00 A.M. to 5:30 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith MacMillan, can be reached at (703) 308-0570.

  
Examiner Joseph W. Ricigliano Ph. D.

Art unit 1627

April 26, 2000